Author's response to reviews

Title: Towards a standardised approach for evaluating guidelines on Palliative Sedation: Study Protocol

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Author's response to reviews: see over
Dear Editor,


Thank you very much for facilitating the revision of the above-mentioned script, and for the opportunity to improve on the previous version.

We have addressed both reviewers’ comments systematically, with a point-by-point description of the changes made and where, in the table below.

Please do not hesitate to contact us if there is need for further clarification.

With kind regards,

Ebun Abarshi,

on behalf of the EURO IMPACT CONSORTIUM
<table>
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<th>Reviewers’ Comments</th>
<th>Authors’ response</th>
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<td><strong>Major compulsory revisions: general</strong></td>
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<td>1. There is a definition of guidance documents, but not of guidelines. Many documents may be titled guideline, but according to which criteria do the authors refer to texts as guidelines? I would like to pose the same question for documents referred to as framework. Considering an unambiguous interpretation of your work by the recipients of your article, I believe a presentation of your definitions for categorization would be useful.</td>
<td>The initial intention was to use the term ‘guidance document’ as an inclusive term referring to all documents that provided sufficient guidance on the subject; i.e. “all guidelines were guidance documents, but not all guidance documents were guidelines”. However in the light of the comment, this term has been revised and separate definitions inserted. It now read thus: A guideline was defined as a systematically developed statement that could be used to facilitate decision making in clinical settings [31], while a guidance document was a less formal and less structured material that simply contained recommendations.</td>
<td>This item has been addressed, and 2 separate definitions are inserted in the revised manuscript, on page 7.</td>
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<td>2. In the manuscript, only in the discussion the term EOL care is used (nowhere written out in full and not defined); it is also used in the checklist, I would like to suggest changing EOL care to palliative care, because there is an ongoing discussion about what is understood by end of life, let alone end-of-life care. Also, the WHO definition (2002) of palliative care includes early integration; therefore the use of this term may be counterproductive.</td>
<td>OK. The acronym “EOL” has been replaced by “palliative” in the entire manuscript and checklist.</td>
<td>We have effected relevant changes in the Discussion section (pages 12-14) and in the checklist (page 3).</td>
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<td>3. The use of the term EOL sedation or EOL sedation</td>
<td>OK</td>
<td>This item is addressed, and relevant</td>
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practice or EOL practice should also be avoided for consistency of the study including use of terms and openness of the study approach to exploring its mayor subject.  

changes have been effected in the Discussion section on pages 12-14 and in the checklist (page 3).  

4. Figure 1 (flowchart) is pretty but doesn’t add much to the manuscript.  
We agree with the reviewer about this.  
The aforementioned flowchart has been deleted.  

**Detailed remarks: manuscript**  

5. Page 4, Background, line 7-9  
For instance, European studies showed the frequency of deep and continuous sedation of patients until death varies between 2.5% of all deaths in 2001 – 2002 (Denmark) and 16.5% of all deaths in 2007 – 2008 (UK) [4, 6].  
Comment: Misleading wording, sounds as if there were a range from 2.5 to 16.5, even though the studies were conducted in different years and it is not clear if the definition of what is meant by the term deep and continuous sedation is identical – better change to European studies showed the frequency of deep and continuous sedation of patients until death varies, for instance 2.5% of all deaths in 2001 – 2002 (Denmark) and 16.5% of all deaths in 2007 – 2008 (UK) [4, 6]… and add information on the comparability regarding definition/procedure.  
We agree that some readers may misunderstand the statement, and have therefore revised it accordingly.  
The statement now reads, “According to European studies, the frequency of deep and continuous sedation of patients until death varies somewhat, though some of such studies were conducted at different times with non-identical definitions. For instance, an incidence of 2.5% of all deaths in 2001 – 2002 (Denmark) and 16.5% of all deaths in 2007 – 2008 (UK) were recently reported [4, 6]”  

6. Page 4, Background  
There appears to be a growing trend in this practice in Europe [4, 23-27], and in the various care settings where people die [25, 26]. Amidst relatively large country variations in prevalence, the actual practice of palliative sedation has been widely reported [27].  
Comment: Considering the rather general remarks more  
We agree that an important point is being made here.  
Given the limited number of references insert-able in the manuscript, we include one additional reference:   - Rietjens JA, Deschepper R, Pasman R, Deliens L. Medical end-of-life decisions: does its use differ in vulnerable patient groups? A
literature from a greater variety of countries and settings should be cited.


Other relevant references have been inserted from the existing bibliography, and the manuscript now reads:

‘There appears to be a growing trend in this practice in Europe [4-6, 23-27], and in the various care settings where people die [25-26, 36]. Amidst relatively large country variations in prevalence, the actual practice of palliative sedation has been widely reported [4-11, 19-20, 27, 33]’ on pages 4-5 of the script.

A list* of other articles supporting this claim is provided below.

<table>
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<tr>
<th>7. EOL care – see above, in general remarks on discussion</th>
<th>We kindly refer to our answer to comment #3.</th>
<th>No alteration is required here.</th>
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<td>8. Page 9-10, Methods To ensure the intentional inclusion of literature published in English, as well as Dutch, Flemish, French, German, Italian and Spanish, we will apply the terms “palliative sedation”, “terminal sedation”, “dying”, “end of life”, “guidelines”, and “framework”, and the following translated terms in varying combinations: palliative sedatie, richtlijn; sédation en médecine palliative, la sédation pour détresse en phase terminale ou en fin de vie, recommandations; guía de sedación paliativa; raccomandazioni, sedazione terminale, sedazione palliattiva; therapeutische palliative sedierung, einsatz sedierender, leitlinie.</td>
<td>The reviewer is correct, in that the added terms vary and were not consistent. The initial search was conducted in English. However, an additional search was done based on cues, such as titles of guidelines and guidance documents identified via the reported survey. We gathered from literature that conventional terms for “palliative care” are not applied in the same manner across Europe: this perhaps is the case</td>
<td>No alteration is required here.</td>
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**Comment:** This list is not consistent. Some of the translated terms are not additional but translations of the above mentioned list, and the choice of additional terms varies in the presented languages.

with “palliative sedation” (although we did not specifically explore this in the study).

The role of this all-inclusive list was to ensure we did not miss eventually relevant documents, but this did not matter much at the end of the day, because only the documents written in accessible languages were reviewed.

**Detailed remarks: additional file checklist**

9. Since the explanatory document to go with the checklist was not submitted, I would like to mention that it should contain definitions of the terms guideline, guidance document, framework etc. as mentioned for the revision of the manuscript (if not already incorporated)

**OK**

A glossary is included in the checklist (on page 8), which clearly states:

- A guideline was defined as a systematically developed statement that could be used to facilitate decision-making in clinical settings.
- A guidance document was a less formal and less structured material that simply contained recommendations.
- A framework is a set of theories that are developed to provide a conceptual understanding of the use of palliative sedation.

10. Part 2: TERMS, DEFINITIONS AND TYPES (14) and (18) change EOL sedation practice to palliative sedation practice or sedation practice for the reasons mentioned in comment 3. I have not found any items on depth of palliative sedation (or overlooked these) – if they are not in, shouldn’t they be incorporated?

Since continuous sedation is incorporated in the answer

The term “EOL care” is replaced with “palliative care” in the manuscript.

Regarding “depth”: this is now clearly differentiated with the following separate answer categories:
- intermittent palliative sedation
- transient palliative sedation

This issue is addressed in Part 2: question 18 (page 2 of the checklist)

Again we concur with the reviewer that the other categories be incorporated in the answer option of (14) and (18); this change has been effected on page 2 of the checklist.
| Option of (14) and (18), intermittent/transient… etc. should also be listed in both | • respite palliative sedation  
• temporary palliative sedation  
• continuous palliative sedation |
|---|---|
| 11. B: COMPARABILITY  
I don’t understand 2.3.b. Does no. 4 in Appendix I of the EAPC document (on which 2.3.b. is probably based) really refer to continuous sedation? I hadn’t thought so. Please check. | Yes it does.  
No alteration is required here. |
| 12. 2.5 Temporary sedation should not stand alone - for consistency of the paper there should be written intermittent/transient/respite/temporary | This has been adjusted accordingly.  
See page 3 of the checklist |
| 13. 3.2. What is meant by relevant investigations? | a. Relevant investigations that exclude acute deterioration from a treatable cause (i.e. sepsis): the item is found on page 584 of the EAPC Framework for further clarification.  
An example of what “relevant investigation” and “treatable cause” mean is inserted in the checklist (on page 3). |
| 14. 4.3.d Here or elsewhere: wouldn’t it make sense to add asking/looking for the planning of the duration and depth of palliative sedation? | Indeed this does make sense. According to the EAPC Framework, ‘asking about /looking towards planning the duration and depth of palliative sedation’ all fall within “preemptive planning”.  
This aspect is revised along the lines mentioned for clarification, and inserted in the relevant section of the checklist: see page 3. |
| 15. 7.9. Why dignified? Is there a definition? | The word ‘dignified’ has been deleted so as not to confuse the reader.  
This section now reads thus: ‘The level of care provided by the team during sedation…’ on page 5 of the checklist. |
<p>| 16. 8.1. “Those involved” is a very unclear term | The term has been deleted because of its irrelevance in the text. |
| 17. 8.2.b. Isn’t that true for any treatment situation? Why do you include an item that reflects a medical error in any treatment situation? | We agree with the reviewer on the point raised, however we chose to maintain some items as they appeared in the EAPC Framework, for the purpose of |</p>
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| **18. 9.1.** Is there a definition of supportive care to which is referred? Also, provide seems a bit ambitious (unless only multidisciplinary teams are addressed), maybe add facilitate or facilitate access to… | The EAPC Framework states “supportive care” should be provided to the members of the patient’s family by the care team, i.e. a multidisciplinary team, and this should include listening to families’ concerns, attention to grief and physical/psychological burdens and guilt. Also, the care team should counsel the family in the ways that they can continue to be of help to the patient, for instance by being with, talking to and touching the patient, providing care, and managing the atmosphere of the patient’s care (e.g. providing the patient’s favorite music, scents, singing favorite songs, saying prayers or reading to the patient).

Therefore supportive care has to be intended as a generic item based on the family’s needs. In this general context, the checklist recommends that it is take into consideration. |
|   | We will not make an alteration in this instance, as we had previously agreed on how the checklist should be read. |
| **19. 9.2., 9.3. and 10.2.** If I understood this right, the information given in the items before was based on checking the documents for content; do 9.2., 9.3. and 10.2. ask for opinions of the respondent which are not to be found in the document. | No. This aspect of the checklist was simply compared with the contents of the guidelines or guidance documents. |
|   | No alteration is required here. |
| **How does this go with the described methodology?** Also, the items in 9.3. Regarding family information needs may suggest that these should be met in which case it should | The methodology points to the fact that the documents are what we plan to examine. The reviewer’s comment here |
| Page 2, Abstract, paragraph 2 | This refers to the additional questions that the authors inserted in the checklist, but which were not explicitly derived from the EAPC Framework. | No alteration is required here. |
| Minor essential revisions | | |
| Corrected. | Correction is effected in the entire manuscript. |
| Discretionary revisions | | |
| Page 4, end of paragraph 1 | This comment has not addressed, given its discretionary nature. Moreover the authors do not think it adds to the paper. | No alteration is applied here. |
| In Google Scholar is also to be found, for example, Neitzke, G., Oehmichen, F., Schliep, H. J., & Wördehoff, D. (2010). Sedierung am Lebensende. Ethik in der Medizin, 22(2), 139-147. | | |
| There is also a new version of the Dutch Guideline dating from 2009 (Royal Dutch Medical Association 2009) – shouldn’t this one be included instead of the older version? | We agree on this. | This is now replaced with: Royal Dutch Medical Association (KNMG). http://knmg.artsennet.nl/Publicaties/KNMGpublicatie-levenseinde/Guidelinefor-palliative-sedation-2009.htm Accessed 27 August 2013. |
Title should be changed to Methods

Page 12, Discussion line 5
Lit 42: correct Schilmann to Schildmann
This has been done. Correction is effected in the text (on page 12).

Section Weaknesses, page 12 f
In this section, the authors only talk about guidelines: In order to be consistent, please change all relevant parts of the text to guidelines and guidance documents.
This has been done. Correction is effected in the text (on page 13).

Some spelling mistakes in the checklist (4/4.3.b)
This has been duly corrected. Correction is effected in the checklist (on page 4).

*List of additional references: